K023108

DEC 0 3 2002

# 510(k) Summary of Safety and Effectiveness

## Atlantic Products, Inc.
## STERIPACK™ Sterile Disposable Syringes and
## STERIPACK™ Sterile Disposable Insulin Syringes

**Contact Person:** Mr. Mahbubur Rahman
Chief Executive Officer
Atlantic Products, Inc.
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Hicksville, NY 11801
Tel: (516) 827-0816
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**Date Prepared:** December 1, 2002

**Device Names:** Brand Names: STERIPACK™ Sterile Disposable Syringe
STERIPACK™ Sterile Disposable Insulin Syringe

Common or Usual Names: Sterile Disposable Syringe
Sterile Disposable Insulin Syringe

FDA Classification Names: Piston Syringe
Piston (Insulin) Syringe

**Predicate Devices:** The STERIPACK Syringes are similar to the following devices:

Becton Dickinson Syringes
Exel Intl Syringes
Nipro Disposable Syringes and Insulin Syringes
Monoject Piston Syringes

All of the devices listed above are either, used for injecting fluids into, or withdraw fluids from, the body, or used for the subcutaneous injection of insulin, and are considered substantially equivalent to the STERIPACK Sterile Disposable Syringe and the STERIPACK Sterile Disposable Insulin Syringe.

**Product Description:**

The STERIPACK Sterile Disposable Syringe, with or without a hypodermic needle, is a sterile, single use, piston syringe, designed for manual use. The STERIPACK Sterile Disposable Syringe is available in 3, 5, 10 and 50 ml volume sizes with luer lock, slip tip, and eccentric configurations.

The STERIPACK Sterile Disposable Insulin Syringe with permanently affixed hypodermic needle, is a sterile, single use, insulin syringe, designed for manual use. The STERIPACK Sterile Disposable Insulin Syringe is available in 0.5 and 1.0 ml volume sizes, color coded with markings for delivery of 100 units of insulin/ml (U-100).

**Intended Use:**

The STERIPACK Sterile Disposable Syringe is intended to be used for injecting fluids into, or withdraw fluids from, the body. The STERIPACK Sterile Disposable Insulin Syringe is intended to be used for the subcutaneous injection of insulin.

**Technology Characteristics:**

The STERIPACK Sterile Disposable Syringe and Insulin Syringe submitted in this 510(k) Notification are substantially equivalent in intended use, technology/principles of operation, materials and performance to the predicate devices listed above. Any differences that do exist do not significantly affect the safety and effectiveness of the STERIPACK Sterile Disposable Syringe and Insulin Syringe.

**Performance Characteristics:**

The STERIPACK Sterile Disposable Syringe and Insulin Syringe comply with ISO 7886-1 (1993) for Hypodermic Syringes, ISO 8537-1991 for Insulin Syringes, ISO 594-1 (1986) for Conical Fittings, and ISO 7864 for Sterile Hypodermic Needles for Single Use.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 3 2002

Mr. Mahbubur Rahman
Chief Executive Officer
Atlantic Products, Incorporated
24 Center Street
Hicksville, New York 11801

Re: K023108
Trade/Device Name: STERIPACK Sterile Disposable Syringe, STERIPACK Sterile Disposable Insulin Syringe
Regulation Number: 880.5860 and 880.5570
Regulation Name: Piston Syringe and Hypodermic Single lumen Needle
Regulatory Class: II
Product Code: FMF and FMI
Dated: September 10, 2002
Received: September 18, 2002

Dear Mr. Rahman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

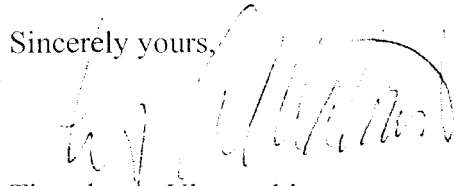
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# 510(k) Premarket Notification
# Indications Enclosure



510(k) Number (if known): K023108

Device Name: STERIPACK Sterile Disposable Syringe
STERIPACK Sterile Disposable Insulin Syringe

Indications for Use:

The STERIPACK Sterile Disposable Syringe is intended to be used for injecting fluids into, or for withdrawing fluids from, the body.

The STERIPACK Sterile Disposable Insulin Syringe is intended to be used for the subcutaneous injection of insulin.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The Counter Use Insulin Syringes
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K023108